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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/361,619 07/27/99 LOOSMORE S 1038-921-MIS

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HM12/0925

AIR MAIL

EXAMINER

ART UNIT	PAPER NUMBER
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1645
DATE MAILED:

09/25/01

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/361,619

Applicant(s)
Loosemore et al.

Examiner
S. Devi, Ph.D.

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 25, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 ~~is/are~~ are pending in the application.
- 4a) Of the above, claim(s) 11-23 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 11
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Applicants' Amendments

1) Acknowledgment is made of Applicants' preliminary amendments filed 09/28/00 (paper no. 7) and 05/25/01 (paper no. 13). The amendment filed 05/25/01 (paper no. 13) identifies and corrects the errors in the SEQ ID identification in claim 1.

Election

2) Acknowledgment is made of Applicants' election filed 09/28/00 (paper no. 7), with traverse, of invention I, claims 1-10, in response to the restriction requirement mailed 08/01/00 (paper no. 5). Acknowledgment is made of Applicants' election of species filed 05/25/01 (paper no. 13), of sequence species, SEQ ID NO: 6, in response to the species election requirement mailed 03/14/01 (paper no. 12).

Applicants state that they agree with the Office's characterization that the subject matter fall into four groups of claims, yet submit that the groups of claims are interrelated and should be examined together. With regard to the species election, Applicants request the Office to reconsider identification of the species among which election is required.

Applicants' arguments have been carefully considered, but are found to be non-persuasive. As Applicants acknowledge, inventions I-IV are distinct from one another. As clearly set forth in the restriction requirement mailed 08/01/00, inventions I and II are drawn to two independent products, a nucleic acid molecule, a vector and a host cell; and an outer membrane protein, respectively. The nucleic acid molecule, for example, of invention I and the outer membrane protein of invention II are distinct from one another structurally, functionally, immunologically and biologically. The methods of inventions III and IV are independent and distinct from one another, because the two methods differ from one another in method steps, parameters and reagent(s) or composition(s) used and the ultimate goals accomplished. Since the four inventions belong to four distinct classes/subclasses, a search for one would not be co-extensive to the other. The species election requirement is also not improper, since the recited SEQ ID No.s are distinct structurally, functionally and biologically. For these reasons, the restriction and the species election requirements are maintained and are hereby made FINAL.

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- 3) Claim 1 has been amended via the amendment filed 05/25/01.

Claims 1-23 are pending.

Claims 11-23 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.

The elected claims 1-10 are under examination. An Action on the Merits for these claims is issued.

Information Disclosure Statements

- 4) Acknowledgment is made of Applicants' information disclosure statements filed 03/22/00 (paper no. 4) and 03/02/01 (paper no. 11). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 14).

Sequence Listing

- 5) Acknowledgment is made of Applicants' CRF/sequence, which has been entered in the case on 01/31/01 (paper no. 10).

Information Disclosure Statements

- 6) Acknowledgment is made of Applicants' Information Disclosure Statements filed 03/22/2000 (paper no. 4) and 03/02/01 (paper 11). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 14).

Drawings

- 7) The drawings are objected to under 37 C.F.R. 1.84 because of the reasons set forth by the Draftsperson in the attached Form PTO 948 (paper no. 14). Correction is required.

Pending Applications

- 8) At the time this Office Action was written, several copending applications related to this case, for example, SN 08/621,944, SN 08/483,855 and SN 08/945,567, were not available to the Examiner of record for review for obviousness type Double Patenting issues. Applicants' assistance is requested in providing the Examiner with a copy of the pending/allowed claims from the above cited pending applications.

Specification - Informalities

9) The specification is objected to for the following reason(s):

The use of the trademarks in the instant specification has been noted in this application. For example, see page 9, lines 17 and 18; and page 33, line 27: "Triton X-100"; see page 28, line 16: "Gem50"; see page 32, line 8: "QIAquick"; see page 34, line 15: "Superdex 200"; and page 37, line 20: "Nunclon". Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

10) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

11) Claims 1-3 and 9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 1 and 3 are indefinite in the recitation "set forth in Figure 3, 4 or 5", 'Figure 8' or 'Figure 9' in claim 3, 'Figure 9' and 'Figure 10' in claim 7; and Figure 19 in claim 8, because the claims fail to point out what is included or excluded by the claim language.

Similarly, claim 2 is indefinite in the recitation 'as identified in Table 1A other than', because the claim fails to point out what is included or excluded by the claim language.

According to M.P.E.P. 2173.05(s), where possible, claims are to be complete in themselves. Incorporation by reference to Tables, Figures, or Examples as in this case, is a necessity doctrine, not for Applicants' convenience. See *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

(b) Claim 9 is vague and indefinite in the recitation "an approximately C-terminal half" (see lines 3 and 4), because it is unclear what is encompassed in this phrase. It is not clear what characteristics a protein or an element should have in order to qualify as "an approximately C-terminal".

(c) Claim 3 is vague and indefinite, because the recitation "being capable of expressing" merely describes the potential capability of the nucleotide sequence to express the

recited protein, but fails to positively recite that the nucleotide sequence in fact expresses such a protein. The rejection can be obviated by changing the phrase "being capable of expressing" to -- which expresses--.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

12) Claims 7 and 8 are rejected under 35 U.S.C § 112, first paragraph, as failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description, e.g. sequenced; or (3) deposited.

Claims 7 and 8 are directed to vectors having the characteristics of the specific plasmids, two having specific ATCC accession numbers (pKS348 and pKS294) and two designated as pQWE and pQWF. It is apparent that the claimed plasmids are required to practice the claimed invention. As a required element, it must be known and readily available to the public, or obtainable by a reproducible method set forth in the specification, or otherwise be readily available to the public. If not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the recited plasmids.

From the specification in lines 25-27 of page 5, it is not clear whether or not plasmids, pQWE and pQWF have been deposited in an acceptable depository. On page 23 of the instant specification, it is indicated that plasmids, pKS294 and pKS348, are deposited at the ATCC. For those plasmids that are not deposited yet, a deposit in an acceptable depository is needed. If the deposit has already been made for certain plasmids under the provisions of the Budapest Treaty, filing of an affidavit or declaration by Applicants or assignees, or a statement by an attorney of record who has authority and control over the conditions of the deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be **irrevocably** removed upon the grant of a patent on this application, is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each state. Further, the statement should identify the deposited plasmids by their depository accession number, establish that the deposited plasmids are the same as those described in the specification, and

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establish that the deposited plasmids were in Applicants' possession at the time of filing.

As a means of satisfying the necessary criteria of the deposit rules and to show that the plasmids deposited are the same as the ones deposited with the specific identification numbers as recited above, Applicants may submit a copy of the contract or a notice of acceptance of the plasmids by the depository.

Applicants' attention is directed to *In re Lundack*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 C.F.R § 1.801-1.809 for further information concerning deposit practice.

Rejection(s) under 35 U.S.C § 102

13) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) The invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14) Claims 1-6, 9 and 10 are rejected under 35 U.S.C § 102(e) as being anticipated by Sasaki *et al.* (US 5,808,024 - Applicants' IDS).

The recitation "another strain" in part (c) of claim 1 is interpreted as any strain of *M. catarrhalis*.

Sasaki *et al.* disclose an isolated and purified nucleic acid molecule having a nucleotide sequence encoding an outer membrane protein of a strain of *M. catarrhalis*, which is characterized by a tract of consecutive 3 base-long G nucleotides and an ATG start codon as recited, and a plasmid or an expression vector for transforming a host comprising the nucleic acid molecule; the host cell is *E. coli* (see abstract; sequence listing; Examples 6, 10 and 11; and paragraph bridging columns 2 and 3). The nucleic acid molecule is from other *Moraxella* strains other than *M. catarrhalis* 4223, Q8 and LES-1 (see Examples 2 and 9-11). Sasaki *et al.* teach a sequence that encodes an N-terminal peptide of the 200 kDa outer membrane protein (see Example 7) and a fragment of SEQ ID 5 (see attached sequence search report).

Claims 1-6, 9 and 10 are anticipated by Sasaki *et al.*

Remarks

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15) Claims 1-10 stand rejected.

16) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week.

17) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 2001


S. DEVI, PH.D.
PRIMARY EXAMINER